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| TRANSMITTAL FORM (to be used for all correspondence after initial filing) | Application Number | 10/713,438 | |
| | Filing Date | 11/14/2003 | |
| | First Named Inventor | Evans, Douglas G. | |
| | Art Unit | 3738 | |
| | Examiner Name | Blanco, Javier | |
| Total Number of Pages in This Submission | 5 | Attorney Docket Number | KN P-0131 |

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| SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT | | | |
|--|-----------------------------|----------|--------|
| Firm Name | c/o Kensey Nash Corporation | | |
| Signature | <i>Jeffrey R. Ramberg</i> | | |
| Printed name | Jeffrey R. Ramberg | | |
| Date | 11/22/2005 | Reg. No. | 34,700 |

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| Typed or printed name | Jeffrey R. Ramberg | Date | 11/22/2005 |

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Evans, Douglas G. et al.
Serial No.: 10/713,438
Filing Date: Nov. 14, 2003

Group Art Unit: 3738
Examiner: Blanco, Javier
Atty. Docket No.: KN P-0131

For: Devices and Methods for Treating Defects in the Tissue of a Living Being

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
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Applicants' Summary of Telephonic Interview

Transmittal

Return Receipt Postcard

11.22.2005

Date

Jeffrey R. Ramberg
Signature

Jeffrey R. Ramberg
Typed or printed name of person signing Certificate



PATENT

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Serial No.: 10/713,438 Examiner: Blanco, Javier G.
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For: Devices and Methods for Treating Defects in the Tissue of a Living Being

APPLICANTS' SUMMARY OF TELEPHONIC INTERVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In regard to the telephonic interview held on November 3, 2005, Applicants provide the following summary.

Participants: for USPTO: Examiner Javier Blanco. For Applicants: Russell Kronengold (co-inventor), Jeffrey Ramberg (Applicants' rep), Jeffrey Kelly (assignee's chief counsel), Steven Link (assignee's co-counsel)

Exhibits shown: none

Claims discussed: none

Identification of prior art discussed: US Patent Application Publication US 2002/0183855 A1 to Yamamoto et al., published on December 5, 2002

Agreement with respect to the claims: not applicable

Substance of interview:

The purpose of the interview was to show differences between the present specification and subject matter disclosed by Yamamoto. In its most basic form, the claimed implant features non-soluble fibers and a flowable biocompatible polymer, thereby imparting to the implant, at least prior to implantation, putty-like consistency. All of the claims were rejected as being anticipated by Yamamoto. Applicants provided at least three areas of difference between their invention and that of Yamamoto.

I. In a preferred embodiment, the claimed implant includes one or more additives, which may be a ceramic particle such as tricalcium phosphate. The ceramic particles are blended or admixed into the system, and typically are held in place by the fibers of biocompatible polymer, not by chemical bonding, as in Yamamoto ("mineralizing"). Dr. Kronengold explained that Yamamoto uses very small particles (less than five microns), and these must be immobilized on the fibers per his specification; which is understandable since particulate of this size can cause an inflammatory response if released into the body. In contrast, immobilization is not required, and actually could not be performed, in the present invention because the ceramic particles are much larger than in Yamamoto (averaging over 100 microns). Indeed, a key aspect of the present invention is the ability to incorporate larger scale particulate, for ease of manufacture and avoidance of inflammatory response.

II. In another preferred embodiment, the claimed invention features collagen fibers as the non-soluble fibers. Dr. Kronengold stated that collagen can organize itself into structures of increasing complexity, and thus exhibits a hierarchy, with soluble collagen or "tropocollagen" being among the simplest forms of collagen, and with collagen "fibrils" being an organized collection of tropocollagen, and still further with collagen fibers being an organized and cross-linked collection of collagen fibrils. The mineralization process specified by Yamamoto, and otherwise known to those skilled in the art (i.e., exposed to a pH of below 3 or above 11) will break down Yamamoto's fiber into fibrils or soluble collagen.

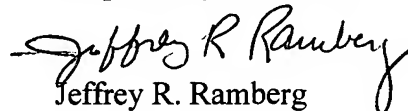
III. Additionally, an aspect of the claimed invention shared by all of the claims is that the implant, at least prior to implantation, has the consistency or viscosity of a putty. As such, the claimed putty, like typical putties, does not exhibit a spring-back effect or "shape memory", but rather, remains in a deformed condition when it is subjected to a shearing stress.

IV. Finally, Yamamoto discusses his materials consisting as a slurry; however, comparing this slurry with the putty-like material of the present invention is not appropriate since Yamamoto's slurry is actually an intermediate material in his process. Yamamoto's final product exists as a semi-solid with shape memory.

In summary, Yamamoto discloses a process which will yield a material consisting of soluble and fibril forms of collagen, which have very fine minerals chemically immobilized on their surface; whereas, the embodiments of the current invention which were discussed, comprise high-order collagen fibers, with relatively coarse ceramic particulate which is constrained mechanically by the physical size of the aforementioned fibers. The additional processing steps discussed regarding the present invention render the material in a putty-like state, and this state does not exhibit the shape memory required by Yamamoto.

Should the Examiner take exception to any of the statements made herein, or deem that any further action on the part of Applicants would be desirable, the Examiner is invited to telephone Applicants' undersigned representative.

Respectfully submitted,



Jeffrey R. Ramberg

Reg. No. 34,700

November 22, 2005

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